stryker

Stryker Europe

URGENT: FIELD NOTICE

Our manufacturer has notified us of a Product Field Action concerning the Medical Devices referenced below. Our records indicate that you have been supplied with some of the subject devices. We would request therefore that you read this notice carefully and follow the instructions provided by the manufacturer.

We would like to reassure you that only the devices listed are affected by this action.

On behalf of Stryker we would like to thank you in advance for your cooperation and support in this matter.

Please note that in accordance with the Medical Device Directive and the Meddev Vigilance Guidance Document this Field Safety Corrective Action has been notified to the National Competent Authority of all countries where subject devices have been distributed.
This Field Safety Notice has been issued in accordance with the European Competent Authority detailed below.

Type of Action	Recall
Date of report	2010-12-08
Stryker Internal Reference Number	RA2010-230
Name of Manufacturer	Stryker Instruments Kalamazoo
Website address	www.stryker.com
National Competent Authority	if appropriate - please delete if not
Regulatory Agency Reference No	if appropriate - please delete if not

Local Contact Information

Contact Person	
Contact tel number:	
Contact e-mail	

Product Information

Product Description	5190 TPS Burs
Product Code/Catalogue No from:	See attachment
Product Code/Catalogue No to:	
Lot Numbers	See attachment
Software version (if applicable)	N/A
Quantities distributed to your facility	
Expiration date of product	January 12, 2010 to June 22, 2011
Expected shelf life/product life	1 year

Issue

Description of problem

These parts are packaged in a flexible foil pouch (0043-445-000), which is supplied by Perfecseal. The pouch is manufactured from two medical grade sheet materials. The foil material provides a high puncture resistant sterile barrier material. The clear film material is sealed to the foil. This is a high puncture resistant sterile barrier and allows the device to be seen within the package. The pouch was incorrectly manufactured using 35709-G material for the film instead of 35721-K. 35721-K film is dimensionally thicker and therefore stronger/more puncture resistant than 35709-G film. 35721-K film was developed for use with the products. The products are aggressive and may require a strong film material to ensure package integrity is not compromised. The products were packaged with 35709-G film, this film is dimensionally thinner and therefore is less puncture resistant than 35721-K. Three defective batches were received from supplier, Perfecseal.

Population concerned

The patient is at risk, particularly when the burr is used in a relatively avascular site such as the tibial shaft or around joint replacements or spinal hardware or the patient is immunocompromised.

Potential Hazards associated with use of device

Product is packaged with out of specification material. The package integrity is breached which may consequently contaminate the device. Potential hazards associated with this occurrence are:

1 The breach is identified before use and results in a delay in surgery of greater than 30 minutes because there is not an alternate product available for use. The probability of this is low because these are single use sterile devices which are usually readily available in hospital inventory.

2 The breach is not noticed and the device is used. This could lead to infection of the surgical site and associated complications for the patient. The probability of this occurrence is low to remote.

Mitigating circumstances/precautionary measures

1. The product has a shelf life of twelve months from the date of manufacture and must be used prior to the shelf life expiry date thereby reducing the exposure time for contamination to occur.
2. The original packaging method when being shipped from Stryker Ireland, should mitigate the risk of packaging damage during this phase of transport and distribution.
3. The labels for each of the devices listed has a symbol which directs the user to "Do not use if package is damaged"
4. The following clinical factors that may mitigate risk are listed in the medical opinion:
4(a). Routine monitoring of burrs and other OR stock and restocking where necessary.
4(b). Careful inspection of packaging.
4(c). Routine use of preoperative antibiotics.
4(d). Routine use of wound irrigation.

Specific advice for surgeons regarding patients with implanted devices

Not applicable - these devices are not implanted.

Communications/Attachments

Customer response form		Indicate number of pages
IFU/User manual/Operative Technique		Indicate number of pages
Upgrade kit		indicate nature of kit
Distribution list		
Labels		
etc		

Immediate Actions

1 Immediately locate and quarantine all subject devices

2 Circulate this list internally to all interested/affected parties

3 Maintain awareness of this of this notice internally until all required actions have been completed within your facility

4 Inform Stryker if any of the subject devices have been distributed to other organisations. Please provide contact details so that Stryker can inform the recipients appropriately.

5 Immediately inform Stryker of any adverse events concerning use/attempted use of subject devices.

6 Comply with any national regulations concerning notification of adverse events to National Regulatory Bodies.

Product Return Information

1 Complete the attached customer response form
(please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notices

2 Return the completed form to:

3 A Stryker representative will then contact you to organise return of subject devices

Name
Position
Signature

RA 2010-230 Affected Products

Part Number	Part Description	Lot Number
5190021775	7.5 x 7.9mm XX CRS DIAMD DRUM, S LONG	9190017
5190021991	9.1 x 7.9mm XX CRS DIAMD DRUM, S LONG	9012017
5190070031	3.1 x 19.1mm STRAIGHT ROUTER, S LONG	9183017, 9202017, 10104017
5190020775	7.5 x 7.9mm FLUTED DRUM, S LONG	9216017
5190020991	9.1 x 7.9mm FLUTED DRUM, S LONG	9089017, 9183017, 10008017, 10173017
5190020105	10.5 x 10.7mm FLUTED DRUM, S LONG	9077017, 10155017
5190020060	6.0 x 7.9mm FLUTED DRUM, S LONG	9189017
5190020123	12.3 x 10.7mm FLUTED DRUM, S LONG	9197017
5190020047	4.7 x 7.9mm FLUTED DRUM, S LONG	9188017
5190013160	6mm XX COARSE RND DIAMD BUR, S LONG	9021017
5190013150	5mm XX COARSE RND DIAMD BUR, S LONG	9188017
5190013140	4mm XX COARSE RND DIAMD BUR, S LONG	9188017
5190013170	7mm XX COARSE RND DIAMD BUR, S LONG	9188017